

Use of a Modified Informed Consent Process Among Vulnerable Patients

Rebecca Sudore, MD
Assistant Professor of Medicine
Division of Geriatrics
University of California, San
Francisco

Background

- Informed consent provides the legal and ethical basis for research & clinical procedures
- However, 40-80% do not understand 1 or more aspects of consent information
- Low literacy likely a factor
 - ~1/2 US adults read \leq and 8th grade level
- Forms written $>12^{\text{th}}$ grade, and complex

Wendler, D. Arch Intern Med, 2004

Joffe, S. Lancet, 2001

Kutner, M. US Dept Educ 2005

Paasche-Orlow, MK. NEJM 2003

Background

- What may be helpful:
 - Improving readability
 - Improving design
 - Allowing time for discussion
 - Using and interactive teach-to-goal strategy

Davis, TC. J Natl Cancer Inst, 1998

Tait, AR. Arch Pediatr Adolesc Med, 2005

Taub, HA. Expr Aging Res 1981 & 1983

Paasche-Orlow, MK Am J Respir Crit Care Med, 2005

Research Goal

- To describe a modified consent process:
 - Consent form written at a 6th grade level
 - Bilingual RAs read the form verbatim
 - Using a “teach-to-goal” strategy for understanding
- To determine:
 - Whether literacy or other characteristics were associated with understanding consent information
 - The number of passes through the consent process to achieve comprehension

Design

- Descriptive study of 205 participants from a county hospital in San Francisco
- Inclusion criteria:
 - Speak English or Spanish
 - Patient in General Medicine Clinic
 - ≥ 50 years
 - Consenting for a trial of 2 advance directives
- Excluded if demented

Modified Consent process

1. Consent form written at 6th grade reading level in English & Spanish
2. Read verbatim in English or Spanish
3. Comprehension assessment:
 - 7 true/false questions about consent content
4. “Teach-to-goal”: repeated, targeted education until comprehension was achieved

Outcome Measure

- Number of passes required to answer all consent comprehension questions correctly.
 - 1 pass (all questions answered correctly)
 - 2 passes
 - ≥ 3 passes

Predictor Variables (Patient Characteristics)

- Literacy, measured by s-TOFHLA (scores 0-36)
 - ≤ 22 considered limited literacy
- Language most comfortable speaking
- Other socio-demographics

Analytic Strategy

- Described participant characteristics and the number of passes required with percentages
- Regression model for # of passes required:
 - Adjusted for age, race/ethnicity, education, gender, language, s-TOFHLA score

Subject Characteristics

N=205

Age \pm (SD)

61 (9)*

Race/ethnicity

White

26%

Latino

31%

Black

24%

Asian/Pacific Islander, Other

19%

Female

53%

Income \leq \$10,000/yr

49%

< High School Education

32%

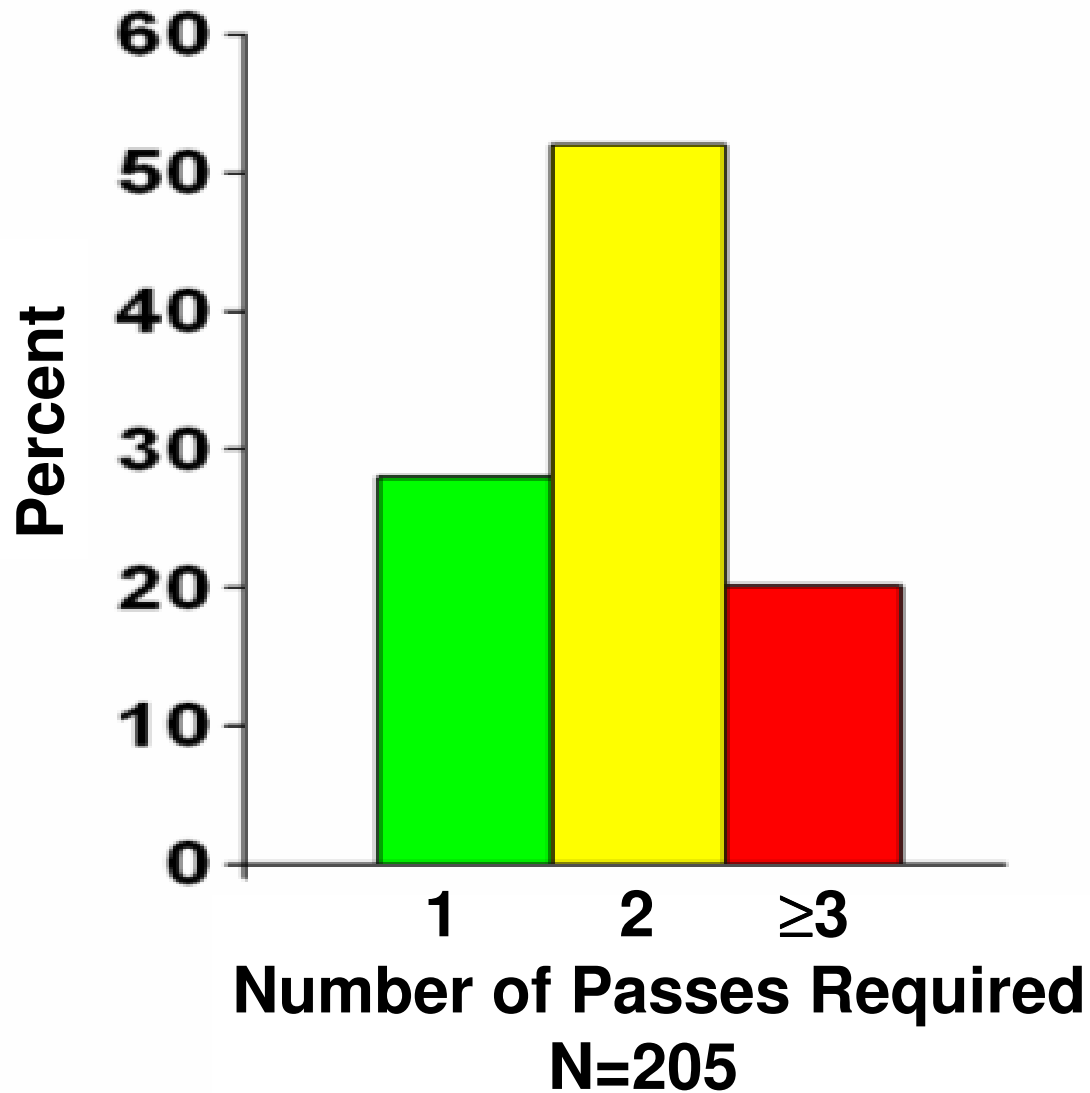
Limited Literacy

40%

Spanish-Speaking

30%

Number of Passes Required to Complete Consent Process

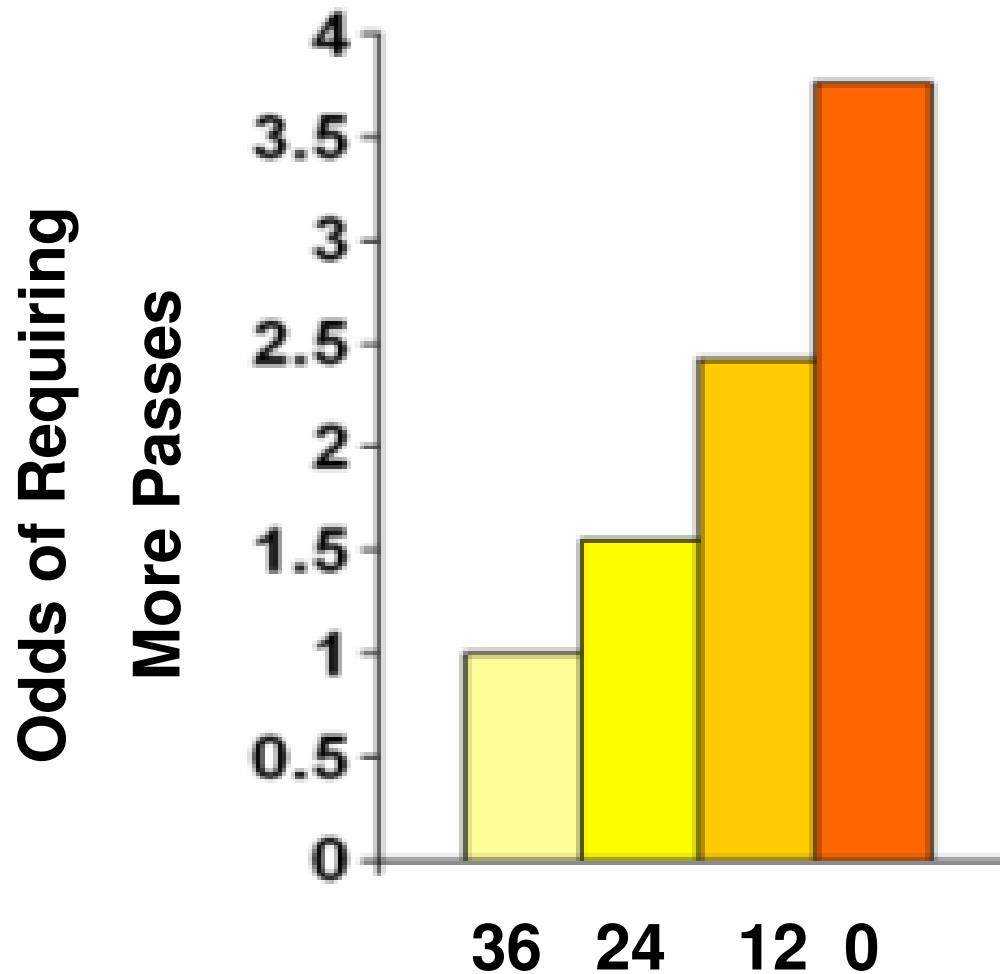


After Adjustment, Literacy and Minority Status Associated with Requiring more Passes

OR (95% CI)

- Black 2.5 (1.1-5.6)
- Literacy:
For every 1 point decrease in literacy score (0-36) 1.1 (1.0-1.1)

As Literacy Score Decreased, Odds of Requiring More Passes Increased



Literacy Score (36 is perfect, 0 is illiterate)

Consent Given in Non-native Language = More Passes

- All Non-native English speakers with limited literacy (n=12) required > 1 pass
- By literacy & language: Who required > 1 pass?
 - **Non-native** English speakers 83%
in highest literacy level (n=6)
 - **Native** English speakers 75%
in lowest literacy level (n=12)

P=.04

Little Effort Required to Consent Most Subjects

- Only 2 passes required to achieve complete comprehension for 80%
- Using teach-to-goal strategy, 98% were able to be consented

Conclusions: The Bad News

- Despite employing a number of consent modifications, most subjects had poor comprehension on the 1st pass
- Low literacy and minority status important determinants of poor understanding
- Regardless of literacy, more passes required if given in non-native language

Conclusions: The Good News

- Using a modified interactive consent process with a teach-to-goal strategy, only modest efforts required to obtain complete understanding and informed consent
- An interactive consent process may improve the quality of consent for diverse populations

Comparison of an Advance Directive Written at a 5th Grade Reading Level vs. a Standard Form

**Rebecca Sudore, C. Seth Landefeld, Deborah Barnes,
Karla Lindquist, Brie Williams, Dean Schillinger**

University of California, San Francisco

Background: Advance Directives (AD)

- ADs are legal documents used to document treatment wishes and designate a surrogate
- Majority of healthcare organizations required to offer patients information about AD
- ADs often not completed. Those most at risk:
 - Minorities
 - Lower socioeconomic status
 - Elderly
- Controversy over effectiveness

Emanuel, LL. NEJM, 1991

www.jcaho.org, 2006

Hofmann, JC. Ann Intern Med, 1997

Fagerlin, A. Hastings Cent Rep, 2004

Advance Directives May Be Unreadable and Intimidating

- 90 million Americans have low literacy
- Mean reading level 8th grade level
For Medicaid recipients and elderly, 5th grade
- AD written at post graduate reading level
- May cause intimidation and low completion

Kutner, M. US Dept of Educ, 2005
Nolan, MT Appl Nurs Res, 2003
Ott, BB, *J Nurs Sch*, 1997

Research Goal

- To examine the association of an advanced directive designed for a low literate population (AD Easy) with rates of:
 - Acceptability
 - Self-efficacy with treatment decisions
 - Comprehension
 - Preference

Compared to a standard advance directive (AD standard)

Design

1st Measures

Demographics
Literacy
Comprehension

AD-Standard

2nd Measures

Acceptability
Self Efficacy
Comprehension

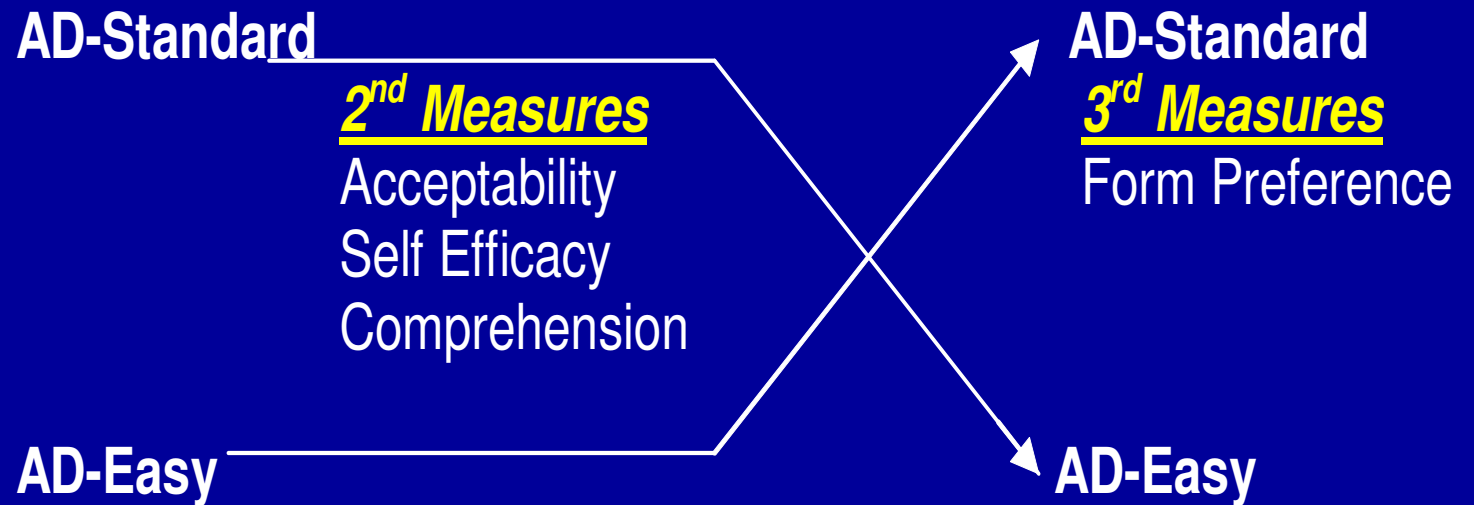
AD-Easy

AD-Standard

3rd Measures

Form Preference

AD-Easy



Study Population

- 205 subjects from an urban county hospital in San Francisco, California
- Inclusion criteria:
 - Speak English or Spanish
 - Patient in General Medicine Clinic
 - ≥ 50 years
- All study questions were read to subjects verbatim in English or Spanish by a native-speaking interviewer

Literacy Assessment

- Short form Test of Functional Health Literacy in Adults
- Validated measure of literacy in the health care setting
- Scores (36 total):
 - ≤ 22 = Limited Literacy
 - > 22 = Adequate Literacy

The AD Forms

- AD-Standard
 - Standard California Advanced Directive
 - Written at a 12th grade reading level*
 - Does not contain graphics
- AD-Easy
 - Written at a 5th grade reading level*
 - Contains culturally appropriate graphics that explain the text
 - English and Spanish
 - Same AD-Standard content, but also a values hx
- Subjects then asked to review alternate form

CALIFORNIA ADVANCE HEALTH CARE DIRECTIVE

Explanation

You have the right to give instructions about your own health care. You also have the right to name someone else to make health care decisions for you. This form lets you do either or both of these things. It also lets you express your wishes regarding donation of organs and the designation of your primary physician. If you use this form, you may complete or modify all or any part of it. You are free to use a different form.

Part 1 of this form is a power of attorney for health care. Part 1 lets you name another individual as agent to make health care decisions for you if you become incapable of making your own decisions or if you want someone else to make those decisions for you now even though you are still capable. You may name an alternate agent to act for you if your first choice is not willing, able, or reasonably available to make decisions for you. (Your agent may not be an operator or employee of a community care facility or a residential care facility where you are receiving care, or an employee of the health care institution where you are receiving care, unless your agent is related to you, is your registered domestic partner, or is a co-worker. Your supervising health care provider can never act as your agent.)

Unless the form you sign limits the authority of your agent, your agent may make all health care decisions for you. This form has a place for you to limit the authority of your agent. You need not limit the authority of your agent if you wish to rely on your agent for all health care decisions that may have to be made. If you choose not to limit the authority of your agent, your agent will have the right to:

- (a) Consent or refuse consent to any care, treatment, service, or procedure to maintain, diagnose, or otherwise affect a physical or mental condition;
- (b) Select or discharge health care providers and institutions;
- (c) Approve or disapprove diagnostic tests, surgical procedures and programs of medication; and
- (d) Direct the provision, withholding, or withdrawal of artificial nutrition and hydration and all other forms of health care, including cardiopulmonary resuscitation;
- (e) Make anatomical gifts, authorize an autopsy, and direct the disposition of your remains.

Part 2 of this form lets you give specific instructions about any aspect of your health care, whether or not you appoint an agent. Choices are provided for you to express your wishes regarding the provision, withholding, or withdrawal of treatment to keep you alive, as well as the provision of pain relief. Space is provided for you to add to the choices you have made or for you to write out any additional wishes. If you are satisfied to allow your agent to determine what is best for you in making end-of-life decisions, you need not fill out part 2 of this form.

Part 3 of this form lets you express an intention to donate your bodily organs and tissues following your death.

Part 4 of this form lets you designate a physician to have primary responsibility for your health care.

After completing this form, sign and date the form at the end. The form must be signed by two qualified witnesses or acknowledged before a notary public. Give a copy of the signed and completed form to your physician, to any other health care providers you may have, to any health care institution at which you are receiving care, and to any health-care agents you have named. You should talk to the person you have named as agent to make sure that he or she understands your wishes and is willing to take the responsibility.

You have the right to revoke this advance health care directive or replace this form at any time.

California Advance Health Care Directive

This form lets you have a say about how you want to be treated if you get very sick.



 This form has 3 parts. It lets you:



Part 1: Choose a health care agent.

A health care agent is a person who can make medical decisions for you if you are too sick to make them yourself.



Part 2: Make your own health care choices.

This form lets you choose the kind of health care you want. This way, those who care for you will not have to guess what you want if you are too sick to tell them yourself.



Part 3: Sign the form.

It must be signed before it can be used.

You can fill out Part 1, Part 2, or both.

Fill out **only** the parts you want.

Always sign the form in Part 3.

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Outcome Measures

- **Acceptability**
 - “Is this form easy to **complete**?”
 - “Is this form easy to **understand**?”
- **Self-efficacy** with treatment decisions
 - “Would this form make it easy for you to **choose** the type of medical care you would want at the end of your life?”
 - “After seeing this form, do you now feel more **confident** in making decisions about your medical care?”
- **Comprehension**
 - Pre to Post test of AD topics (12 pt)
- **Preference**
- **6-month AD Completion Rates**

Analytic Strategy

- Outcomes described as percentages
- Stratified Analyses:
 - Literacy Level (Limited/Adequate)
 - Language (English/Spanish)

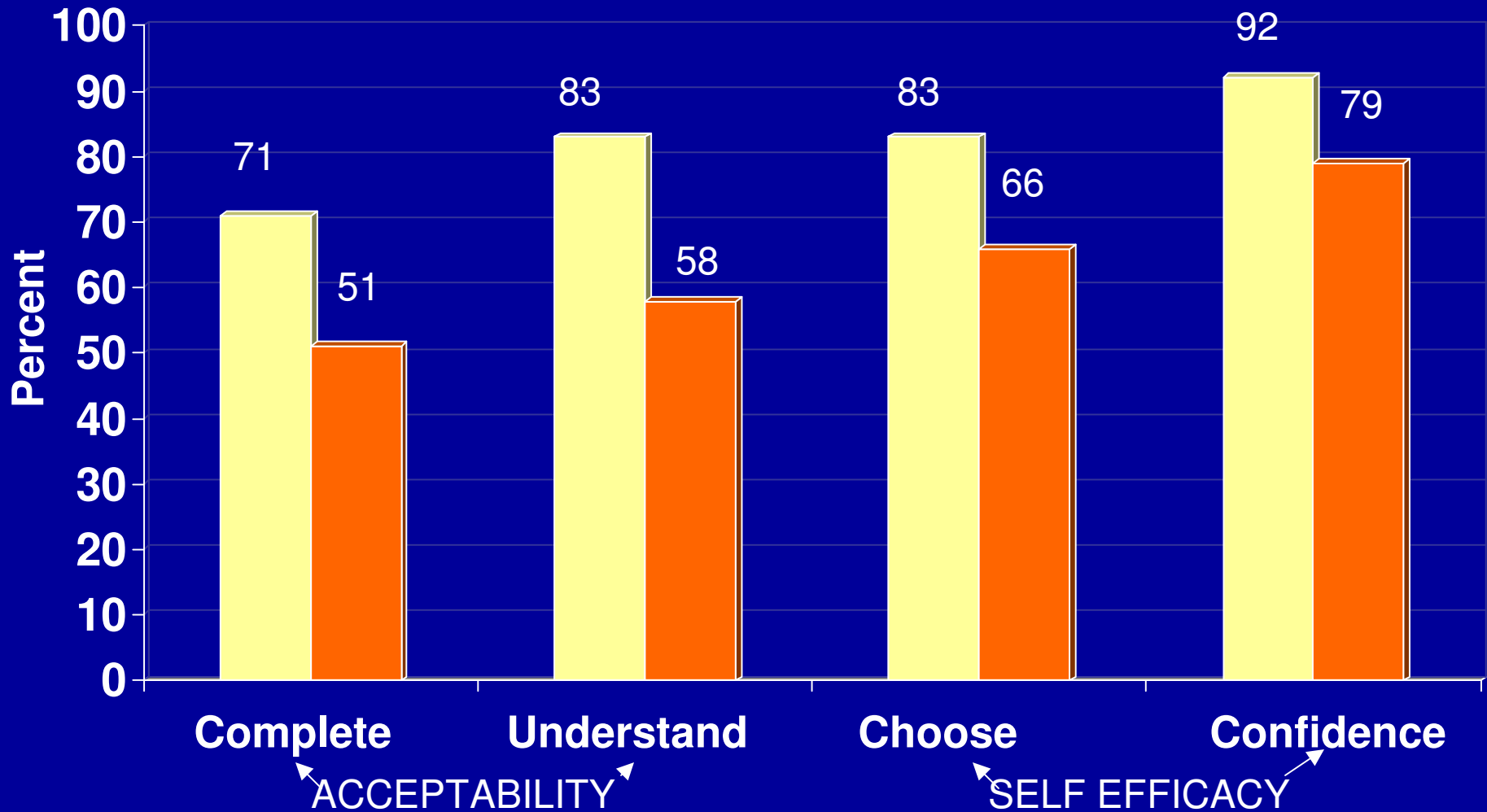
Subject Characteristics

N=205

Age \pm (SD)	61 (9)*
Race/ethnicity: White	26%
Female	53%
Income \leq \$10,000/yr	49%
< High School Education	32%
Limited Literacy	40%
Spanish-Speaking	30%
Medical Problems \pm (SD)	3 (1.4)
Hospitalizations in 2 yrs \pm (SD)	1 (1.2)
Fair to Poor Health	67%
Prior Completion of an AD	<u>13%</u>

The AD-easy: More Acceptable and Higher Self-efficacy, n=205

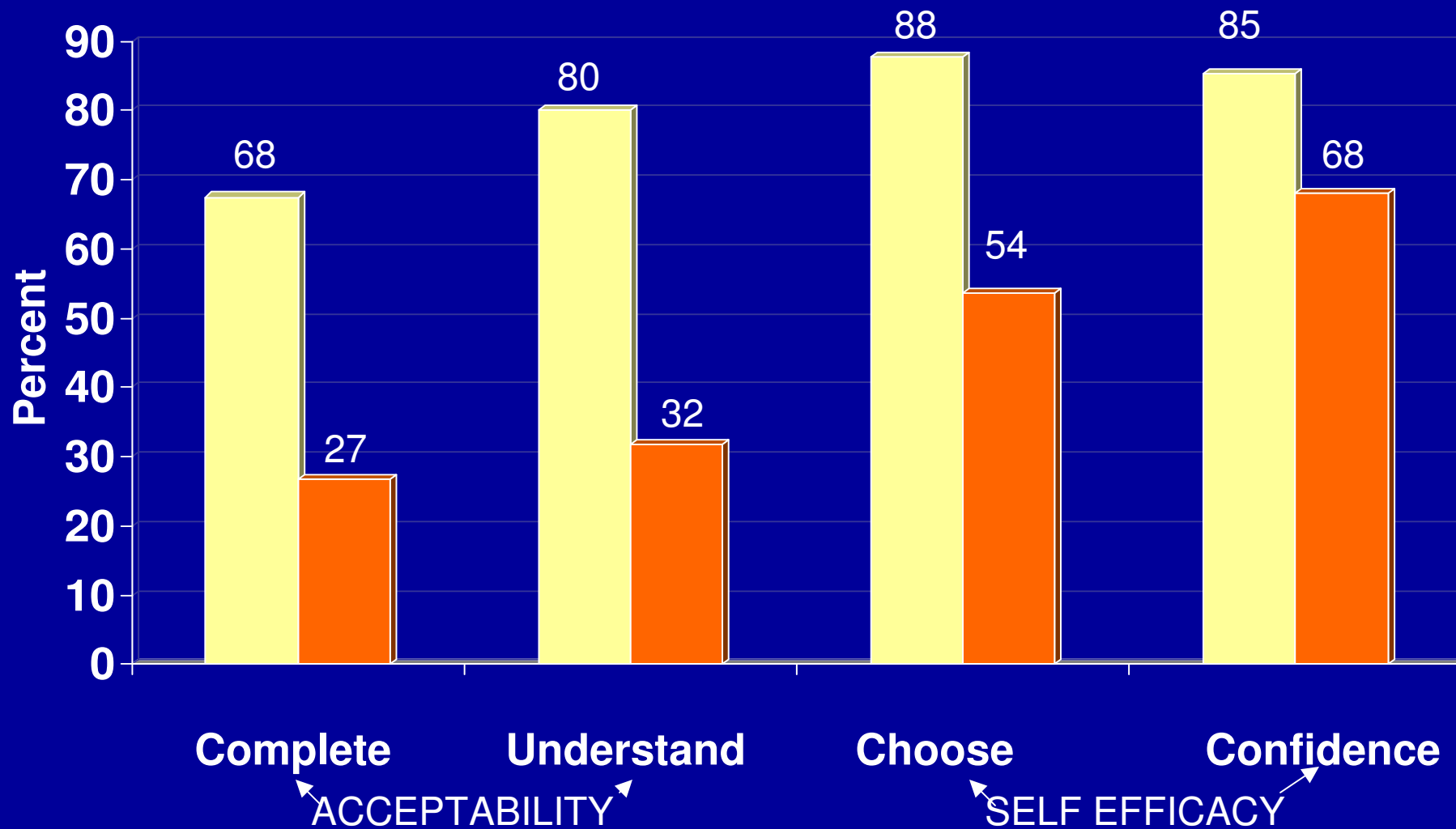
■ AD-Easy ■ AD-Standard



All p-values <.01

Acceptability and Self-efficacy, Among Subjects with Limited Literacy, n=82

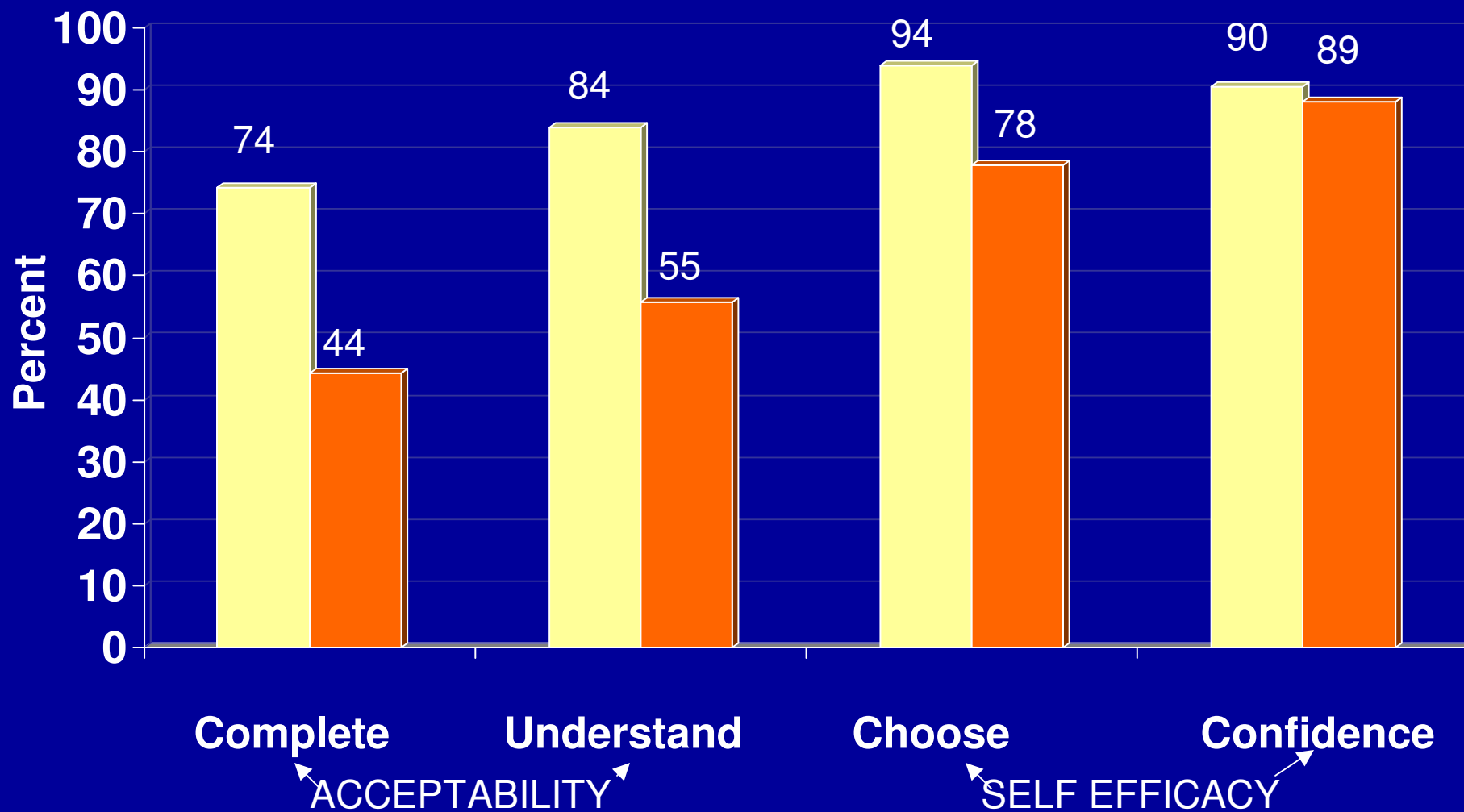
■ AD-Easy ■ AD-Standard



All p-values <.01

Acceptability and Self-efficacy, Among Spanish-speakers, n=59

■ AD-Easy ■ AD-Standard



All p-values <.02, except Confidence

AD-Easy, Some Comprehension Improvement

Change in pre to post Comprehension score (total 12 pts)	AD-Easy	AD-Standard	P-value
Overall Improvement	1.5	1.0	.11
Improvement by Literacy			
Limited Literacy	1.2	1.2	1.0
Adequate Literacy	1.6	0.89	.02
Improvement by Language			
Spanish	1.2	1.4	.56
English	1.6	0.88	.03

AD-Easy is Preferred over the AD-Standard

	N=205	P-value
Overall Preference for AD-Easy	81%	-----
Preference for AD-Easy by Literacy		
Limited Literacy	88%	.06
Adequate Literacy	77%	
Preference for AD-Easy by Language		
Spanish	85%	.35
English	79%	

6-Month AD Completion Rates

- N = 173, 84% follow-up rate
- 22 participants (13%) filled out a new AD
- By Randomization Group:
 - AD-Easy = 18.5% P=.03
 - AD-Standard = 7.7%
- Which Form was completed:
 - 21 filled out AD-Easy
 - 1 filled out AD-Standard

Summary and Conclusions

- AD-Easy was associated with greater
 - Acceptability
 - Self-efficacy
 - Overwhelmingly preferred
- AD-Easy particularly benefited subjects with literacy and language barriers
- The rate of 6-month AD completion rates doubled from baseline and almost all subjects filled out the AD-Easy
- Future research is needed:
 - to explore whether AD-easy can improve discussions, and treatment decisions aligned with wishes.

Thanks to:

Dean Schillinger, MD

C. Seth Landefeld, MD

Institute for Health
Care Advancement

Form is available for
free download in
English, Spanish, &
Chinese:

iha4health.org

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